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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,450	01/26/2001	Lawrence I. Kruse	ADOL-0497	4357

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/769,450	KRUSE ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25 and 27-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25 and 27-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted July 16, 2004 is acknowledged.

1. The terminal disclaimers filed on July 16, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,239,154, 6,476,063, 6, 486,165 and 6,492,351 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting Rejections

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25, 27-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15, 25-27 of copending Application No. 10/455,687; and claims 4-6 of copending application 10/455,545. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in the co-pending application are directed to method of treating or preventing pruritis by administering compounds known as kappa opioid receptor agonists. The compounds employed

in those claims are species of kappa opioid receptor agonists. Regarding the particular dosage and the particular administration method, note the optimization of a result effective parameter, e.g., dosage and method for administration of a known pharmaceutical agents, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

2. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Note terminal disclaimers mentioned in the response have not been submitted with the response filed July 16, 2004.

Claim Rejections 35 U.S.C. 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 25, 27-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite 'kappa opiate receptor agonist is an amine-containing, non-peptide, arylacetamide compound which is substituted with at least one polar group, and wherein said kappa agonist is devoid of central nervous system effects' which encompasses much larger scope than herein disclosed (pages 99-112 in the specification). The specification provide no written description with respect to the compounds other than those disclosed herein. Further, the application as originally filed does not support such subgenus of arylacetamide with an amine

group. In one particular aspect, the application fails to provide a sufficient direction, guidance for how to attached the polar group. Page 12 in the application disclosed that the identity and position of the polar group is important. However, as to arylacetamides other than U50,488, the application provides no information as to the identity and position for the polar groups. Therefore, the application lack a proper written description for the compounds encompassed within the claimed scope.

5. Claims 25, 27-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for particular compounds disclosed herein in the specification as kappa opioid receptor agonists, see page 99-112 in the specification, does not reasonably provide enablement for other agents which may meet the limitation of 'kappa opiate receptor agonist is an amine-containing, non-peptide, arylacetamide compound which is substituted with at least one polar group, and wherein said kappa agonist is devoid of central nervous system effects'. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant uses functional limitation ''kappa opiate receptor agonist is an amine-containing, non-peptide, arylacetamide compound which is substituted with at least one polar group, and wherein said kappa agonist is devoid of central nervous system effects' to defined the agents employed in the method. A person of ordinary skill in the art would have been required to perform undue experimentation to use claimed invention, particularly, to identify and make those 'arylacetamide non-peptide kappa opioid receptor agonists' within claimed scope. Attention is directed to In re Wands, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue

experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

The claim recites the employment of 'arylacetamide non-peptide kappa opioid receptor agonists' which would encompass any non-peptide compounds with an arylacetamide moiety, and which may function as kappa opioid receptor agonists. There are unlimited number of non-peptide compounds with an arylacetamide moiety. The specification or the claims provide no information or guidance as to the structural requirements that would make the arylacetamide to be a Kappa opioid receptor agonist. As evidenced by US patents 6,316,461, and the other patents cited in the double patenting rejection, the skilled artisans are exploring a variety of compounds which fall within non-peptide arylacetamide, and which may function as kappa opioid receptor agonists. These compounds may be form many patentable distinct groups, and each of them may warrant separated U.S patent. There is no way to identify those compounds except try and fails. Applicants fail to provide information allowing skilled artisan to ascertain these compounds without undue experimentation. The pharmaceutical art is unpredictable, requiring each

embodiment to be individually assessed of physiological activity. The instant claims read on all ''kappa opiate receptor agonist is an amine-containing, non-peptide, arylacetamide compound which is substituted with at least one polar group, and wherein said kappa agonist is devoid of central nervous system effects', necessitating an exhaustive search for the embodiments suitable to practice the claimed invention, absent undue experimentation. In one particular aspect, the application fails to provide a sufficient direction, guidance for how to attached the polar group. Page 12 in the application disclosed that the *identity and position of the polar group is important.* However, as to arylacetamides other than U50,488, the application provide no information as to the identity and position for the polar groups. There for the application are not enabled for compounds other than those specifically disclosed.

Response to the Arguments

Applicants' amendments and remarks submitted July 16, 2004 have been fully considered, but are not persuasive with respect to the rejections set forth above.

Particularly, the specification fails to provide a proper written description to satisfy the full scope of the claimed invention. The application provides written description to a particular group of compound represented by the Formula group I-IV, but fails short to the extent of the full scope of claimed invention. As discussed above the claimed scope is much large than those compounds represented by formula I-IV. For example, the claimed compounds would cover compound employed in WO 98/23290 (IDS), some of which are structurally distinct from formula I-IV. The specification certainly does not provide written description for those compounds.

Applicants' arguments regarding the enablement rejections under 35 U.S.C. 112 are not persuasive. Particularly, the addition of the limitation "amine-containing," and "substituted at least one polar group" provide no help to devoid or rebuttal the rejections. "Amine-containing" provide little, or no help for ordinary skill in the art to find those arylacetamide kappa opiate agonists since amine containing is not a sufficient condition to render an arylacetamide the kappa opiate agonist property, which also required being lack of central nervous effect. With regard to the "substituted with at least one polar group" as discussed above, Page 12 in the application disclosed that the *identity and position of the polar group is important*. However, as to arylacetamides other than U50,488, the application provide no information as to the identity and position for the polar groups. There for the application are not enabled for compounds other than those specifically disclosed.

Applicants argue that the rejections provide no technical reasoning to support the rejection. Applicants' attention is directed to following statements made in the prior office action: "The claim recites the employment of 'arylacetamide non-peptide kappa opioid receptor agonists' which would encompass any non-peptide compounds with an arylacetamide moiety, and which may function as kappa opioid receptor agonists. There are unlimited numbers of non-peptide compounds with an arylacetamide moiety. The specification or the claims provide no information or guidance as to the structural requirements that would make the arylacetamide to be a Kappa opioid receptor agonist. As evidenced by US patents 6,316,461, and the other patents cited in the double patenting rejection, the skilled artisans are exploring a variety of compounds which fall within non-peptide arylacetamide, and which may function as kappa opioid receptor agonists. These compounds may be form many patentable distinct groups, and each of them may

warrant separated U.S patent. There is no way to identify those compounds except try and fails. Applicants fail to provide information allowing skilled artisan to ascertain these compounds without undue experimentation. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed of physiological activity. The instant claims read on all 'arylacetamide non-peptide kappa opioid receptor agonists', necessitating an exhaustive search for the embodiments suitable to practice the claimed invention, absent undue experimentation."

Applicants further contend the examiner's assertion of lacking direction, guidance, and working examples, citing the more than one hundred examples disclosed in the specification. It is noted that number of examples cannot fully reflect the broadness of the scope. The content of the examples need to be considered. In the instant case, all the more than a hundred examples shows no thing beyond the scope defined by formula I-IV, thus do not support the full scope as herein claimed.

to applications 10/455,687, 10/455,545.

3. Note terminal disclaimers mentioned in the response have not been submitted with the response filed July 16, 2004.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617